Section 6

Opioid Treatment Program Standards

A. Intent

Opioid treatment programs provide rehabilitation and medical support for persons addicted to opioid drugs. The duration of treatment should be based on the needs of the persons served and should take into consideration the benefit of medication. Medications used to achieve treatment goals include methadone or Levo-alpha-acetyl-methadol (LAAM). The standards and interpretive guidelines in this section address the unique characteristics and practice guidelines of Opioid Treatment Programs consistent with federal regulations and CSAT guidelines.

Services are directed at reducing or eliminating the use of illicit drugs, criminal activity, or the spread of infectious disease while improving the quality of life and functioning of the persons served. Opioid treatment programs follow rehabilitation stages in sufficient duration to meet the needs of the persons served. These stages include initial treatment of 0 to 7 days in duration, early stabilization lasting up to 8 weeks, long-term treatment, medical maintenance, and immediate emergency treatment when needed.

B. Documentation

The numbers in parentheses refer to the standards in this Standard that require documentation.

- Licenses and certificates. (Standard 1, page 118)
- Policies and procedures. (Standard 2, page 120)
- Community relations plan. (Standard 3, page 123)
- Annual training plan. (Standard 7, page 125)
- Record of staff training events. (Standard 7, page 125)
- Screening documentation. (Standard 8, page 126)
- Assessment documentation. (Standard 10, page 127)
- Written informed consent. (Standard 13, page 131)
- Orientation. (Standard 15, page 132)
- Community resources file. (Standard 18, page 136)
- Medication documentation. (Standard 24, page 141)
- Dosage documentation. (Standard 25, page 141)
- Criteria for unsupervised medication. (Standard 27, page 142–143)
- Criteria for quantity of unsupervised medication. (Standard 28, page 143)
- Medical withdrawal documentation. (Standards 30, 31, pages 144–145)

Applicable Standards

All organizations applying for accreditation are responsible for meeting all standards in Sections 1, 2,

3, 4, and 5. A number of standards in this section specifically address treatment issues from previous sections. Policies and procedures directly related to opioid treatment programs are included in standard 6.C.2.

Due to the specific regulations which govern treatment, the interpretive guidelines in this section should be treated as both extensions and explanations of the standards. **For the standards in Section 6 only, programs are to demonstrate conformance with the standards as well as their interpretative guidelines.**

C. Structure and Staffing

[Ref.

Sec. 1.B.1.]

1. The opioid treatment program should have a program sponsor. The responsibilities of the program sponsor include:

a. Providing clean and well-maintained buildings and equipment. The program's facilities should offer:

(1) A convenient and accessible location.

(2) Private offices for counseling.

(3) Maintenance of the safety and security of records.

(4) Adequate facilities for medication dispensing and physical examinations.

b. Providing a stable, therapeutic environment that includes:

(1) Friendly and engaging staff members.

(2) Consistently assigned personnel and scheduled rehabilitation activities.

(3) Services and hours of operation that meet the needs of the majority of persons served.

c. Protecting and promoting the rights of the persons served.

d. The recruitment, training, and supervision of all staff members.

e. The implementation and annual review of all policies and procedures in conformance with local, state, and federal regulations.

f. Maintaining all necessary licenses and certifications in conformance with local, state, and federal regulations.

Interpretive Guidelines

1. The role of the program sponsor may be different from the role of the designated authority. See standard 1.B.1. in Section 1.A program sponsor is a person or representative of an organization who is responsible for the operation of the program and who assumes responsibility for all its employees.

1.a.(3) Programs are to ensure confidentiality of all records by using locked file cabinets or a locked records room. While the interpretive guideline related to standard 1.B.7. indicates that locked file cabinets are not necessary, regulations related to opioid treatment require that the record storage areas be locked.

Additionally, programs should have:

- Procedures to address the referral of individuals and transfer of records.
- Records retention for a minimum of three years.
- A process for the destruction of old containers, labels, printouts, and clinic records.

1.b.(2) The program should have a stable staffing pattern achieved by either assigning the same personnel to the program or by rotating personnel from a consistent pool to provide for the needed intensity of interventions on a consistent basis.

1.b. (3) The program's services and hours of operation, including evenings, weekends, and holidays, are evaluated periodically to ensure that the services are available and accessible to meet the needs of the majority of persons served.

1.c. In addition to the standards contained in Section 4.A., Rights of the Persons Served, programs are to ensure that the rights of the persons served address:

- Services provided in the least restrictive environment.
- Adequate and humane service.
- Information about alternative treatments, medications, modalities, and scientific evidence regarding treatment.
- Access to the record by the person served with clinical staff supervision.
- Timely response to requests for copies of the records of the persons served.
- Protection from the behavioral disruptions of other persons served.
- Equal access to treatment for all persons in need regardless of race, ethnicity, gender, age (with specific reference to policies for minors), sources of payment, and sexual orientation.

Individuals have the right to be informed of appeal procedures, have the right to initiate appeals, have posted grievance procedures in conspicuous places, receive a decision in writing, and be able to appeal to unbiased sources. See the related standards regarding grievance procedures in Section 4.A.

1.f. Overall program responsibilities include maintaining the necessary licenses and certification needed for the provision of opioid treatment such as DEA (Drug Enforcement Administration) documentation, state methadone authority requirements, and FDA approval. The program sponsor needs to maintain documentation that meets all local and state safety and environmental codes (See Section 3). Program sponsors ensure that all programs adhere to federal confidentiality regulations (42 CFR Part 2).

[Ref. Sec. 1.B.1., 3.B., 4.B., 4.C., 5.B.1]

2. Programs should implement and consistently apply written policies and procedures that address:

a. Responsibilities of the program sponsor.

b. Screening, admission, assessment, and individual planning.

c. Medication management to include:

(1) The responsibility of the medical director, other physicians, and other health care professionals.

(2) The role of physicians regarding admission and dosage.

(3) Establishing the initial and maintenance dose.

(4) Unsupervised dosing.

(5) Emergency administration of medications.

(6) Diversion control plan.

(7) Medicating traveling persons.

(8) Safe storage practices for unsupervised medications to include the use of child-proof or child-resistant containers.

d. Drug-screening procedures to include:

(1) Frequency of and individualized approach to drug screening.

(2) Ensuring respect for the persons served during urine sample collection.

(3) Testing for opiates, methadone, amphetamines, cocaine, and barbiturates, at a minimum.

(4) Interpretation of the results and action taken.

(5) Minimizing falsification during urine sample collection.

(6) Medically-oriented, specimen-handling procedures.

e. Other laboratory procedures.

f. Counseling and education.

g. Treatment and referral for coexisting health issues.

h. Needs of special populations to include:

(1) Women.

(2) Pregnant and postpartum women.

(3) Adolescents.

(4) Criminal justice referrals.

(5) Persons with infectious diseases.

i. Withdrawal procedures should address:

(1) Voluntary, medical withdrawal.

(2) Withdrawal against medical advice.

(3) Involuntary administrative withdrawal.

(4) Referral and discharge.

j. Emergency medical procedures.

k. Program contingency procedures.

l. Critical incidents and threats.

m. Research activities.

Interpretive Guidelines

2.a. See standards regarding Program Sponsor.

2.b. See related standards in Section 4.

2.c. See related standards in Section 5.

2.c.(1) The medical director or program physician should be responsible for ordering medications for each person served prior to initial dosage. The medical director and physician may be the same person in many programs. The medical director, physicians, nurse practitioner, or physician assistant are responsible for:

- Physical examinations.
- Participation in treatment planning.
- Determining frequency of unsupervised medications and program attendance.

2.c.(6) The diversion control plan should ensure quality care while minimizing the diversion of methadone and/or LAAM from treatment to illicit use. The plan needs to include:

- Clinical and administrative continuous monitoring.
- Problem identification, correction, and prevention.
- Accountability to the person and community.

2.d.(1) After admission, the frequency of drug screening will depend on clinical indicators and treatment. Testing is often more frequent in the initial stages of treatment and later reduced. Testing should be structured to respond to the possibility of relapse. At least eight random drug screens are required to be completed for each person served per year.

2.d.(2) Urine and other toxicological specimens should be collected in a manner that communicates trust and respect while taking reasonable steps to prevent falsification of samples. Reliance on direct observation, one-way mirrors or video cameras, although necessary for some, is neither necessary nor appropriate for all persons served.

2.d.(3) Urine testing for other drug use should be determined by community drug use patterns or individual medical indications. Other tests should be based on the needs of the persons served, local drug use trends, and funding limitations.

2.d.(4) Drug screening results should be:

- Addressed with the persons served once the results are available, in order to intervene with drug use behavior.
- Documented in the record of the persons served.
- Reviewed for false negative and false positive results.

2.g. Co-existing health issues may include:

- Mental health problems.
- Use/abuse of other licit and illicit drugs and/or alcohol.
- HIV or other sexually transmitted diseases.
- Infectious diseases.
- Pregnancy and prenatal care.

Persons who are HIV-positive are offered options to balance opioid treatment and HIV care. Linkages with HIV treatment facilities are developed to ensure continuation of opioid medication as AIDS becomes a

primary health concern. Programs should develop procedures which include methods for monitoring or dispensing medication for mental illness by mental health providers.

2.h.(4) Procedures should include cooperative agreements with the criminal justice system to encourage continuous treatment of individuals incarcerated or on probation and parole.

2.i.(1) Withdrawal should be initiated only when strongly desired by the persons served. Voluntary, medical withdrawal refers to initiation by the persons served and/or requested dose reduction.

2.j. Emergency medical procedures describe:

- Steps to follow in the case of an overdose or severe drug reaction. See Standard 3.B.26.
- Names and telephone numbers of individuals (e.g. physicians, hospitals, EMT's) who should be contacted in case of an emergency. These numbers should be displayed in all facility offices and the lobby. See Standard 3.B.27.
- During all hours of operation, at least one staff member should be trained and hold current certification in emergency first aid and CPR. See Standard 3.B.25.

Emergency procedures may include:

- Disaster plans. Refer to Section 3.
- Links to community agencies for emergency dosing.
- Steps to be taken in the event of a medical emergency, overdose or severe drug reaction.

2.k. Such contingencies may include program closure, inclement weather, change of ownership, and emergencies.

2.l. Written procedures regarding adverse events should address (See Standard 3.B.19):

- Physical and verbal threats.
- Violence.
- Inappropriate behavior.
- Dangerous situations.
- Medication errors.
- Deaths.
- Selling drugs on premises.
- Harassment and abuse.
- Procedures to implement during adverse events include:
    - Full documentation of the adverse event.
    - Prompt review and investigation.
    - Implementation of timely and appropriate corrective action.
    - Ongoing monitoring of corrective action plans.

2.m. See the related standard in Section 4. Programs are encouraged to participate in research activities as long as it does not compromise the treatment process. All research should adhere to sound research principles, be conducted in conformance with federal regulations regarding human subjects. Individual treatment should not be jeopardized if the person served refuses to participate in research activities.

[Ref. Sec. 1.A.4.]

3. A written community relations plan with documented community activities should be implemented to include:

a. Soliciting community input regarding the impact of the program.

b. Educating groups about substance abuse and the use of methadone/LAAM in treatment.

c. Identifying staff member(s) to serve in community relations activities.

d. Developing written procedures to address and resolve community relations problems such as loitering, diversion, and theft.

e. Prominently displaying all licenses and certifications.

Interpretive Guidelines

3.b. Community activities and contracts should be documented to identify trends and problem resolution. Community groups and organizations may include:

- Publicly elected representatives.
- Health and human service agencies.
- Hospitals.
- Businesses.
- Community and health planning agencies.
- Grassroots community organization leaders.
- Police and law enforcement officials.
- Religious leaders.
- Neighbors.

[Ref. Sec. 5.A.12.]

4. Services should be provided by an interdisciplinary team of qualified and experienced staff composed of at least a:

a. Licensed physician.

b. Licensed nurse and/or pharmacist.

c. Primary counselor.

Interpretive Guidelines

4.a. Depending on local, state, and federal laws and regulations, state licensed or certified healthcare professionals with privileges to prescribe medication such as physicians, physician assistants, and/or nurse practitioners can perform functions normally performed by licensed physicians.

4.b. This staff person can be a licensed nurse or pharmacist or a person licensed under appropriate state law and qualified to dispense opioid drugs. This licensed practitioner assumes responsibility for the amounts of opioid drugs administered or dispensed. The practitioner also records and appropriately initials or countersigns all changes in dosing ordered by the physician or prescribing professional.

4.c. It is preferred but not required that the primary counselor be licensed or certified in the state where

the program is located. Refer to related standards in Section 1.D.

[Ref. Sec. 1.D.1., 5.A.3]

5. Programs should provide availability to staff 7 days a week, 24 hours a day.

Interpretive Guidelines

5. The standard does not require staff to be on site at all times but at least one designated staff member is available "on call" for emergencies of the persons served and the verification of dosage levels.

[Ref. Sec. 5.A.4.]

6. The program should have a qualified medical director whose responsibilities include:

a. Administering all medical services.

b. Admitting each person served.

c. Ensuring that the program is in conformance with all applicable local, state, and federal regulations regarding the medical treatment of opioid addiction.

d. Ensuring that all medical examinations and laboratory studies have been performed.

Interpretive Guidelines

6. The medical director's qualifications should include:

- Possession of a license to practice medicine in the state or jurisdiction in which the program is located.
- Demonstrated experience in opioid treatment programs.
- Knowledge of local, state, and federal regulations regarding the dispensing of methadone/LAAM.

6.a. A physician has authority over all medical aspects of care. The physician has the authority to make treatment decisions consistent with the needs of the persons served, clinical protocols, and research findings.

6.d. The medical director or physician will review all records of the persons served and verify that all medical examinations and laboratory studies have been performed and recorded.

[Ref. Sec. 1.D.10., 1.D.11., 3.B.23., 3.B.25.]

7. Staff training related to opioid treatment should:

a. Be provided to new staff members prior to the delivery of services.

b. Include an annual training plan for all direct service staff members.

c. Include a record of staff training events.

d. Include regular, continuous training related to:

(1) Clinical and pharmacotherapy issues.

(2) Behavior management regarding physical and verbal threats, acts of violence, inappropriate behavior, and other potentially dangerous situations.

(3) First aid, CPR, overdose, and other emergency procedures.

(4) Special populations to include women, adolescents, and seniors.

(5) Resources for problem solving and troubleshooting.

(6) Infectious diseases.

Interpretive Guidelines

7. Behavioral health professionals who work in opioid treatment programs face a unique delivery system with both opportunities and challenges. The intent of this standard is to ensure that individuals new to this setting receive full and complete training prior to the delivery of services and throughout their employment, and that evidence of such training is documented in the personnel charts.

7.c. The record of staff training should include:

- Qualifications of trainers.
- Content outline.
- Description of methods.
- Record of attendees.

7.d.(1) All staff members should understand the benefits and limitations of drug screening and other tests.

D. Admission and Assessment

8. The program physician must document that treatment is medically necessary.

9. Criteria for admission should be based on the definition of opioid dependence in the *Diagnostic and Statistical Manual of Mental Disorders* (Fourth Edition) *(DSM-IV).*

Interpretive Guidelines

9. Behavior supportive of a diagnosis of addiction includes:

- Continuing use of the opiate despite known adverse consequences to self, family, or society.
- Obtaining illicit opiates.
- Using prescribed opiates inappropriately.
- One or more unsuccessful attempts at gradual removal of physical dependence on opioids (detoxification) using methadone. This is also called medically supervised withdrawal (MSW). An unsuccessful attempt at MSW is evidenced by uncontrollable drug craving (or actual use) caused by insufficient methadone dose during an admission for detoxification or MSW. There should be no artificial barrier created nor should there be a set amount of time that separates the transfer from an unsuccessful attempt at detoxification or MSW directly into the early phase of methadone/LAAM maintenance treatment.

There may be individuals in special populations who have a history of opioid use but who are not currently physiologically dependent. The absence of physiological dependence should not be an exclusion criterion, and admission is clinically justified. This is because individuals in these populations are susceptible to relapse to opioid addiction leading to high-risk behaviors with potentially life threatening consequences. These populations include the following:

- Persons recently released from a penal institution.
- Persons recently discharged from a chronic care facility.
- Pregnant patients.
- Previously treated patients.
- Adolescents.

[Ref. Sec. 4.B.3.]

10. The initial screening should document eligibility and medical necessity of opioid treatment and include:

a. Evidence of tolerance to an opioid.

b. Current or past physiological dependence for at least one year prior to admission.

c. Multiple and daily self-administration of an opioid.

Interpretive Guidelines

10. A person reentering treatment may need to repeat all or portions of the assessment depending on when the original assessment was conducted.

When establishing a diagnosis of opioid addiction, programs should refer to the appropriate diagnostic manuals such as *Diagnostic and Statistical Manual for Mental Disorders (DSM-IV)* or *International Classification of Diseases (ICD-9).* In addition to the above admission criteria, the following behavioral signs which support the diagnosis should be documented:

- Unsuccessful efforts to control use.
- Time obtaining drugs or recovering from the effects of abuse.
- Continual use despite harmful consequences.
- Obtaining opiates illegally.
- Inappropriate use of prescribed opiates.
- Giving up or reducing important social, occupational, or recreational activities.

Individuals should not be admitted to opioid treatment programs to receive opioids for pain only. Staff should make the diagnostic distinctions between the disease of opioid addiction and the physical dependence associated with the chronic administration of opioids for the relief of pain. While both individuals may exhibit physical dependence, tolerance, and similar drug-seeking behaviors, the seven criteria for substance dependence included in the *Diagnostic and Statistical Manual for Mental Disorders* (*DSM-IV,* p. 181) should guide the diagnosis. Relevant criteria to distinguish chronic pain from opioid addiction are:

- Unsuccessful efforts to control use.
- Large amounts of time spent in activities to obtain drugs or recover from the effects of use.
- Giving up or reducing important social, occupational, or recreational activities.
- Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
- An interdisciplinary team that includes the availability of pain and addiction medicine specialists

should treat individuals with both a chronic pain disorder and active opioid addiction.

10.a. The program physician may waive the criteria of physical dependence or one-year history of addiction, when the person seeking admission meets one of the following criteria:

- The person has been recently released from a penal or chronic care facility with a high risk of relapse.
- The person has been previously treated and is at risk of relapse.
- Pregnant individuals who do not exhibit objective signs of opioid withdrawal or physiological dependence.

11. The physical examination and related laboratory work should be conducted within seven days of admission. The examination should include, at a minimum:

a. A urine drug screen.

b. A TB skin test and chest x-ray if the skin test is positive.

c. Screening for syphilis and other infectious diseases.

Interpretive Guidelines

11. The physical examination should include a medical history, an examination of body systems, and be completed by a Doctor of Medicine, Doctor of Osteopathy, physician assistant, or nurse practitioner with knowledge and documented experience in addictions. The physical examination will focus on clinical signs, complications of addiction (liver problems, multiple traumas, etc.) and symptoms of addiction (i.e. needle marks, constricted or dilated pupils, eroded or perforated nasal septum and the state of sedation or withdrawal characterized by yawning, restlessness, irritability, chills, perspiration, nausea, or diarrhea). Based on an individual's history and physical examination, programs investigate the possibility of infectious disease, pulmonary and cardiac abnormalities, dermatologic sequelae of addiction, and possible concurrent surgical and other problems.

The medical laboratory analysis includes complete blood chemistry and urine laboratory evaluations. Other tests may include:

- Complete Blood Count (CBC).
- Routine chemistry profile and drug screening panel.
- Chest x-ray if TB skin test is positive.
- Screening tests for infectious diseases, HIV, and STD's, and counseling.
- EKG
- Pap smear.
- Screening test for sickle cell anemia.
- Hepatitis B surface antigen (HbsAG) and Hepatitis B surface antibody (Anti-HBs).
- Testing for Hepatitis C.
- Testing for other drugs based on individual medical indicators and community drug use patterns.

The medical and laboratory evaluation may be complicated at admission by financial and transportation problems, or poor physical or mental health. Other tests may be deferred until the person served has stabilized.

11.b. A chest x-ray should be performed in the instance of documented or suspected anergy.

[Ref. Sec. 4.B.9.]

12. The multidisciplinary psychosocial assessment process should be completed within thirty days of admission. The assessment should include:

a. Determination of current physical dependence and addiction.

b. The assessment of the medical and family history.

c. Psychiatric history and mental status examination.

Interpretive Guidelines

12. A comprehensive assessment should be completed once the person served is stabilized. The assessment is included in the record of the person served. In addition to all standards described in Section 4, the psychosocial assessment for opioid treatment will include:

- A description of the historical course of the addiction to include drugs of abuse such as alcohol and tobacco including the amount, frequency of use, duration, potency, and method of administration; previous medical withdrawal and/or treatment attempts; and any psychological or social complication.
- A health history should collect information regarding chronic or acute medical conditions such as HIV, STD's, Hepatitis (B, C, Delta), tuberculosis, diabetes, anemia, sickle cell trait, pregnancy, chronic pulmonary diseases, and renal diseases.

The initial assessments focus on the admission to treatment by the person served and on determining dosage level. A more comprehensive examination is performed within approximately 30 days when the person served is stable and better able to participate. Other evaluations that may prove necessary include formal psychiatric and vocational assessments, and ancillary medical workups. The program is responsible for arranging such evaluations and for follow-up. A person reentering treatment may need a repeat examination depending on the timing of the original exam. All persons served also undergo periodic health assessments including regular screenings based on clinical guidelines as appropriate for age and gender.

Assessments generally comprise an intake screening assessment and an intensive initial evaluation. The screening is conducted to determine whether the person served may appropriately receive methadone/LAAM therapy. The intensive evaluation includes medical and health history, and physical examination to determine initial dosage and to place the person into the appropriate level of treatment. Upon completion of proper consent, the program seeks medical records from other health care providers. The health history is used to determine the length of dependence for placement purposes and to identify other chronic or acute medical conditions that affect the health of the person served.

Psychosocial assessment employs a multidisciplinary evaluation approach. Such an approach may be conducted by multidisciplinary team members. As an alternative, this evaluation may be conducted by one or more individuals, but must evaluate the following areas–medical, psychosocial, vocational, educational, behavioral, marital, financial, legal, health, and self-care needs of the person served. This evaluation should be conducted within approximately 30 days of initiation of patient treatment. Assessment updates and treatment plan updates should be conducted quarterly for the first year of continuous treatment and semiannually for subsequent years.

12.a. Each program determines current physical dependence and addiction. History, examination, and

screening are used to determine the person's current degree of dependence on narcotics and, to the extent possible, the length of time the person has been dependent on opioids. This assessment includes a physical examination for the presence of clinical signs of addiction, such as old and fresh needle marks, constricted or dilated pupils, and/or an eroded or perforated nasal septum and a state of sedation or withdrawal. The examination evaluates the observable and reported presence of withdrawal signs and symptoms, such as yawning, rhinorrhea, lacrimation, chills, restlessness, irritability, perspiration, piloerection, nausea, and diarrhea.

12.b. Each program documents medical and family history. A complete medical history, including current information to determine chronic or acute medical conditions, such as diabetes, renal diseases, hepatitis B, C, and delta, HIV exposure, tuberculosis (TB), sexually transmitted diseases (STDs), other infectious diseases, sickle-cell trait or anemia, pregnancy (including past history of pregnancy and current involvement in prenatal care), and chronic cardiopulmonary diseases is documented. Programs complete a full medical evaluation within 7 days of treatment initiation. The program completes information on the family of the person served, including sex and date of birth of children, whether children are living with parents, and family medical and drug use histories.

12.c. Each program completes a psychiatric history and mental status examination with *DSM-IV* categorization as part of a general medical evaluation.

[Ref. Sec. 4.A.1.]

13. Programs should obtain written informed consent of the person served prior to initiating treatment. Such informed consent should address:

a. Voluntarily choosing to participate in the program.

b. Federal confidentiality regulations.

c. The facts and risks concerning all treatment procedures including the use of methadone/LAAM.

d. The following expectations:

(1) The natural history of opioid addiction is altered by time and history.

(2) The goal of methadone/LAAM medication therapy is stabilization of functioning.

(3) At periodic intervals, in full consultation with the person served, the provider will discuss present level of functioning, course of treatment, and future goals. These discussions are in no way intended to place an unfair burden or pressure on the person served to withdraw from or maintain the person served on the medication unless medically indicated.

Interpretive Guidelines

13. Refer to Section 4 regarding additional information to be provided to the person upon admission. The written informed consent and related documentation such as travel forms, take home medication, and unsupervised medication documentation should be in the record of the person served.

13.b. The informed consent should include state-specific requirements to report suspected child abuse and neglect as well as other forms of abuse such as domestic violence.

13.c. The informed consent should identify permission to use the specific prescribed medication before

dosing begins.

14. Programs should demonstrate efforts to prevent individuals from being enrolled in more than one opioid treatment program.

Interpretive Guidelines

14. Measures to prevent multiple enrollments should protect the confidentiality of the person served. Such methods may include:

- National and state admission database or central registry.
- Collecting previous and current treatment information at screening.
- State authority documentation.
- Informal arrangement with other programs.
- Program Services.

[Ref. Sec. 4.B., 4.C., 4.D., 5.A.1,2., 5.B.]

15. Programs should directly provide, contract or make referrals for the following services, based on the needs of the persons served:

a. Screening and assessment.

b. Individual treatment planing.

c. Orientation.

d. Individual, group, and family counseling and education for addictions and mental health issues.

e. Medical care (physical examinations, laboratory work, medical evaluations, prenatal care, pain management, etc.).

f. Vocational and employment services.

g. Testing, counseling, and education regarding HIV, Hepatitis B, Hepatitis C, tuberculosis, and sexually transmitted diseases.

h. Observed medication dispensing, pharmacotherapy, and management.

i. Drug screening.

j. Emergency medical services.

k. Crisis intervention.

l. Continuing care.

m. Advocacy and self-help groups.

n. Follow-up and outcome management.

Interpretive Guidelines

15. Individuals normally proceed from one stage of treatment to the next, or move back and forth due to relapse and other complicating events. These stages of treatment (described in the program description for this section) follow the natural course of the disease and clinical protocols. The treatment tasks are determined in relation to the person's stage in the disease. All stages of treatment need to be of sufficient intensity and duration to be effective.

The intent of this standard is to ensure that opioid treatment programs offer a full array of rehabilitation services and provide more than medication dispensing. A program that only dispenses medication would not conform to this standard. The program sponsor should document in the record of the persons served, and other program documentation that the listed services are available to all persons served and actually provided.

Services of greater intensity are typically necessary at the beginning of treatment. Medication and other services may be needed for extended periods of time based on the needs of the persons served. Every effort should be made to retain persons in treatment as long as clinically appropriate, medically necessary, and acceptable to the persons served. Additionally, pharmacotherapy may benefit the individual person even when he or she does not appear to be benefiting from other services. Programs should ensure that services and space requirements adhere to state and DEA requirements.

15.b. The individual plan should be in the record of the person served and be reviewed at least quarterly for the first year of continuous treatment and at least semiannually for subsequent years. Documentation should ensure that all services listed in the treatment plan are available and have actually been provided.

15.d. Programs provide counseling of the duration and intensity to meet the needs of the persons served. Counseling should address, at a minimum:

- Treatment and recovery objectives, as well as potential health concerns like HIV and other infectious diseases.
- No limits on psychosocial services when a person is not receiving medication.
- Concurrent alcohol and drug abuse.
- The involvement of family and significant others with the informed consent of the persons served while protecting their confidentiality.
- Specialized treatment groups.
- Choice and guidance in seeking alternative therapies.

15.e. Primary medical care on-site is recommended but not required. When managing persons with chronic pain, programs should consult with a specialist in pain management, continue regularly scheduled dosing, and prescribe additional medication when clinically indicated.

15.g. Programs should provide counseling on HIV and STD's with particular emphasis on prevention. Programs should offer on-site HIV testing as appropriate while maintaining confidentiality. Staff should be trained on the current prevention and treatment of persons with HIV and STD's and be knowledgeable regarding HIV testing and interpretation of test results.

15.j. When access to a comprehensive treatment program is not feasible, provisions for opioid agonist therapy can be provided in such settings as emergency rooms, detention centers, AIDS hospice programs, and prisons. Such conditions requiring emergency medical treatment could include pregnancy, HIV-spectrum diseases, and general medical and psychiatric illnesses.

15.k. Every state has established regulations for the involuntary hospitalization of individuals who are typically determined to be a threat to themselves or another individual. Staff should demonstrate

knowledge of the laws and procedures for involuntary hospitalization.

15.l. Continuing care should include discharge planning and relapse prevention.

15.m. The program should encourage persons to use self-help and advocacy groups supportive of opioid treatment. Programs can establish their own self-help programs or identify groups that are accepting of maintenance pharmacotherapy. The use of self-help should not be a requirement, but a recommendation since all persons in opioid treatment may not benefit from involvement with self-help groups.

15.n. Programs are to follow-up with the persons served after treatment. Refer to Section 2.C. regarding outcome management standards. Outcome effectiveness measures for opioid programs should include improved functioning such as:

- Reduction or elimination of abuse of licit and illicit drugs.
- Reduction or elimination of criminal behavior.
- Reduction or elimination of behaviors related to the spread of infectious diseases.
- Improvement of quality of life.

[Ref. Sec. 3.B.23., 4.B.6., 5.B.5.]

16. The documented orientation for opioid treatment should include:

a. The nature of addictive disorders and recovery including misunderstandings regarding opioid treatment.

b. Program rules including those related to noncompliance, discharge procedures, and withdrawal.

c. Rights of the persons served and confidentiality.

d. Signs and symptoms of overdose and when to seek emergency assistance.

e. Characteristics of the prescribed medications.

f. HIV and other infectious diseases.

g. Drug safety issues.

Interpretive Guidelines

16.b. It should be documented in the record of the persons served that the following was discussed and the person was provided a copy of:

- Program rules and regulations.
- Rights and responsibilities of the persons served.

16.e. Characteristics include:

- Dispensing procedures.
- Side effects
- Drug interactions.
- Drug screening procedures.

16.g. Methods employed to notify the person served of his or her responsibilities might include:

- Posted notification.
- Orientation.
- Individual and group counseling sessions.
- Education sessions.
- Patient handbook.
- Informing program personnel of changes in drug use.
- Reporting to other medical service providers the status of the persons served as participants in an opioid treatment program.

[Ref. Sec. 4.B.12., 4.C.5.]

17. Services should be provided, or referrals made, for individuals who have co-occurring health and psychosocial issues.

Interpretive Guidelines

17. Such co-occurring health and social issues or needs may include:

- Medical problems.
- Other addiction problems.
- Chronic pain disorder.
- Mental health and family problems.
- Use/abuse of multiple drugs and/or alcohol.
- HIV or other sexually transmitted diseases.
- Infectious diseases.
- Pregnancy and prenatal care.
- Pregnancy and HIV infection.
- Vocational and employment needs.
- Legal service needs.

Screening for such issues occurs at the time of admission and should involve the use of the appropriate medical laboratory tests. The program establishes and utilizes linkages with community-based treatment facilities. The program has an established set of procedures for referring individuals to physicians when the treatment of their co-occurring disorder warrants a referral.

Individuals with a chronic pain disorder only, and not opioid addiction, are generally not admitted to opioid treatment. However individuals with chronic pain disorder and physical dependence on opioids can receive opioid agonist therapy for either maintenance or withdrawal if the program is the only available source of treatment.

Concurrent abuse of other drugs is managed within the context of the methadone/LAAM therapy effort following principles described in TIP 10, *Assessment and Treatment of Cocaine-Abusing Methadone-Maintained Patients,* and TIP 7, *Treatment of Opiate Addiction with Methadone.*

Program staff are knowledgeable about current, effective strategies for treating alcohol, cocaine, and other drug abuse.

Ongoing multi-drug use is not necessarily a reason for discharge unless the persons served refuses recommended, more intensive levels of care. Persons engaging in such multi-drug use must be carefully evaluated to determine the most therapeutic course of treatment, in light of the fact that many persons (and communities) continue to benefit from methadone/LAAM therapy even when the persons served are not fully abstinent from all drugs of abuse. In addition, the condition of the person served and the best clinical judgment of the treatment team must also be taken into account.

When possible, comorbidities are concurrently managed on-site. This includes management of multiple drug use problems as well as psychiatric and medical disorders. Coexisting conditions, especially in persons from disenfranchised populations, are most effectively treated at a single site.

Pregnant women in opioid therapy with concomitant HIV infection are subject to the same policies and procedures established for all HIV-infected patients in treatment and receive the same services. They are informed that AZT is currently recommended to reduce prenatal transmission of the HIV infection, and they are offered a referral for treatment and care management.

18. A community resource file should be developed, maintained, and used for proper referral and placement of the persons served.

Interpretive Guidelines

18. A community resource file should contain a listing of services, fees, hours of operation, the contact person as well as material to be provided to the persons served. Programs should support and provide guidance for persons who choose to seek alternative therapies. Information on community resources such as transportation, hospital emergency services, ambulance services, and information and referral services should be made available to the persons served through program personnel.

[Ref. Sec. 4.A.1., 4.A.4., 5.A.12.]

19. When providing services to women, the program should:

a. Provide counseling regarding women's issues, violence, sexual abuse, and pregnancy.

b. Provide the appropriate physical space to meet their needs.

c. Assign counselors and specialized groups based on the needs and desires of the persons served.

Interpretive Guidelines

19.b. The safety of female clients should be a primary concern for the program. All women should feel safe while in the facility. The emotional climate is one that is respectful of women and ensures the maintenance of their dignity. Procedures regarding the appropriate use of the physical space should be established, for bathrooms, observable drug screening, etc.

19.c. The program ensures that staff members are sensitive to the specific needs of women. All staff members receive inservice training that addresses these needs. The program should have access to staff members who are qualified to counsel women regarding violence, neglect, and sexual abuse.

[Ref. Sec. 4.A.1.]

20. When providing services to pregnant women, the program should address:

a. Accepted medical practices and dosing strategies during pregnancy.

b. Priority in initiating opioid treatment.

c. Access to prenatal care, education, and postpartum follow-up.

Interpretive Guidelines

20. The reason for denying admission to any pregnant women should be documented.

20.a. The dosing strategy throughout the pregnancy should follow usual and customary dosing principles of the program, unless adjusted by the program physician. Pregnant individuals who choose to withdraw from treatment against medical advice may do so under the direct supervision of a physician experienced in addiction medicine. The dosing of pregnant women should be carefully monitored especially during the last trimester of the pregnancy. Women who become pregnant while active participants in the program are maintained on pre-pregnancy doses if effective, and the same dosing principles are applied as with any other person served who is not pregnant. The program encourages breastfeeding unless otherwise medically contraindicated such as in cases of HIV-positive infection and concurrent drug use.

20.c. If prenatal care is not available on site or by referral, or if the person can not afford or refuses prenatal care, the program should offer prenatal instruction such as maternal, physical, and dietary care as part of the documented counseling and education activities. If the person refuses prenatal care, the program should document the refusal in the record of the person served. Programs should provide or make referrals for parenting skills and reproductive health services for males and females and their partners.

Prenatal care not only includes physical examinations but also education. This care may be provided either on site or by referral. This care should include education regarding fetal development, care for the newborn, breastfeeding, the effects of maternal drug use on the fetus, information on parenting, and the importance of sound maternal nutritional practices. The program should recognize that the person served has the right to refuse prenatal care.

Before discharge, the program will identify the physician to whom the person served is being discharged. The name, address, and telephone number of the physician should be recorded in the record of the person served.

[Ref. Sec. 4.A.1., 4.B.7., 4.B.9., 4.C.4., 4.D.2.]

21. When providing services to adolescents, programs should:

a. Provide developmentally appropriate assessment, instructional, and counseling services.

b. Ensure the safety of the person served.

c. Identify cases of abuse and neglect.

d. Provide referrals for special needs.

Interpretive Guidelines

21.The program should follow state regulations regarding the treatment of individuals under 18 years of age. In the situation where the state does not have any special requirements for the treatment of persons under 18 years of age, the program should secure the consent of a parent or guardian.

In order to be eligible for maintenance treatment, the program should document two attempts at short-term detoxification or drug-free treatment. The physician should document in the record of the person served continued physical dependence on a narcotic drug.

21.a. The program offers instruction that is developmentally appropriate and provides information regarding the use of drugs, HIV, and other health related matters.

21.b. The program has procedures to ensure that adolescents are not harassed, violated, or abused by staff, older persons, or other adolescents.

21.d. Adolescents who need special medical care are referred to a physician who has clinical experience in working with adolescents and addictions. Adolescents should be monitored for treatment reactions that may be developmentally detrimental. A plan should be in place in the event that special medical care is required.

22. The program should adhere to the *Consumer Bill of Rights and Responsibilities.*

Interpretive Guidelines

The Advisory Commission on Consumer Protection and Quality in the Health Care Industry was appointed by President Clinton on March 26, 1997, to "advise the President on changes occurring in the health care system and recommend measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system." As part of its work, the President asked the Commission to draft a "consumer bill of rights." The following rights and responsibilities have been drawn up by the Commission and have been made a part of these Guidelines:

- The persons served have the right to receive accurate, easily understandable information. Some require assistance in making informed health care decisions about their health plans, professionals, and facilities.
- The persons served have the right to a choice of health care providers that is sufficient to ensure access to appropriate high-quality health care.
- The persons served have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a consumer presents to an emergency department with acute symptoms of sufficient severity–including severe pain–such that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing that consumer's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.
- The persons served have the right and responsibility to fully participate in all decisions related to their health care. The persons served who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators.
- The persons served have the right to considerate, respectful care from all members of the health care system at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system.
- The persons served must not be discriminated against in the delivery of health care services consistent with the benefits covered in their policy or as required by law based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.
- The persons served who are eligible for coverage under the terms and conditions of a health plan or

program or as required by law must not be discriminated against in marketing and enrollment practices based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

- The persons served have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. The persons served also have the right to review and copy their own medical records and request amendments to their records.
- All persons served have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.
- In a health care system that protects consumers' rights, it is reasonable to expect and encourage the persons served to assume reasonable responsibilities. Greater individual involvement by the persons served in their care increases the likelihood of achieving the best outcomes and helps support a quality improvement, cost-conscious environment.

E. Medication Management

[Ref. Sec. 5.B.4.]

23. Medications used in the treatment of opiate addiction should be:

a. Sufficient to produce the desired response for the desired length of time.

b. Approved by the Food and Drug Administration for the treatment of opioid addiction.

c. Dispensed according to product labeling, and in the case of methadone, in liquid form only.

d. Managed to ensure secure storage, accurate dosage, and follow-up accounting for unsupervised doses in conformance with DEA regulations.

Interpretive Guidelines

23.a. Factors in setting dose include:

- Results of the physical examination.
- History of narcotic dependence.
- Current standards of practice.
- Dosage required for stable function.
- Evaluation of continued unauthorized drug use.
- Withdrawal.
- Use of prescribed medication.

The total dose and interval between doses may require adjustments and allow for a margin of safety and effectiveness based on individual metabolic patterns or other medications that may affect metabolism.

Opioid therapy should produce the following clinical effects:

- Prevent the onset of abstinence symptoms for at least 24 hours.
- Reduce or eliminate drug craving.

- Block the effects of other opiates without producing euphoria or other undesirable effects.

23.b. Currently, only methadone and LAAM (Levo-Alpha-Acetyl-Methadol) are approved for use in treatment programs. Only methadone is currently approved for dispensing for unsupervised use. When prescribing LAAM, programs should conform to specific regulatory requirements.

23.d. The program physician should justify any deviations from doses, frequencies, and conditions of usage described in the approved product labeling.

[Ref. Sec. 5.B.2., 5.B.7.]

24. When dispensing methadone or LAAM, the program should:

a. Ensure that each medication and/or dosage change is ordered and signed by a program physician.

b. Ensure that each dose is recorded, both in the patient record of the person served and on medication sheets in a manner sufficient to maintain an accurate inventory of all medication in stock at all times. The documentation should include:

(1) The signature or initials of the qualified person administering medication.

(2) The exact number of milligrams of the substance dispensed with daily totals.

c. Develop a procedure for calibrating medication-dispensing instruments consistent with manufacturer's recommendations to ensure accurate dosing and tracking.

Interpretive Guidelines

24.b.(1) If initials are used, the full signature should be entered at the bottom of each page of the medication sheet.

[Ref. Sec. 5.B.3.]

25. The initial dose of methadone or LAAM should:

a. Be individually determined by a physician after an initial examination.

b. Not exceed 30 mg. (methadone only).

Interpretive Guidelines

25.a. A physician, or other medical professional licensed to prescribe medications, should base initial dosage on sound clinical judgment. The initial dose of LAAM, or other approved medications, should follow product labeling. Any deviation from product labeling should
be documented in the record of the person served.

25.b. Programs should obtain medication blood levels when clinically indicated. The usual initial dose of methadone typically should not exceed 30 mg. and the initial total daily dose for the first day should not exceed 40 mg. Justification for exceeding this initial dose (i.e. dosage did not suppress opiate abstinence symptoms) should be documented in the record of the person served.
If dosage exceeds 40 mg. for the first day, the physician should justify that 40 mg. did not suppress the abstinence symptoms after three hours of observation following the initial dose. Individuals using diverted medical opioids may require lower initial doses.

In determining practice guidelines for prescribing the initial dose of LAAM, please refer to LAAM in the Treatment of Opiate Addiction, Treatment Improvement Protocol (TIP) Series, No 22, Substance Abuse and Mental Health Administration, Center for Substance Abuse Treatment, DHHS Publication no. 95-3052, 1995.

[Ref. Sec. 5.B.3.]

26. A physician should individually determine the adequate maintenance dose of methadone or LAAM to meet the needs of the person served.

Interpretive Guidelines

26. A physician, or other medical professional licensed to prescribe medications, should base maintenance, take-home or withdrawal dosage on sound clinical judgment. The physician makes the decision regarding dosage with support and recommendations by a multidisciplinary team. Dosage of methadone should not be manipulated to reinforce positive behavior or to punish negative behavior. Neither should the dose be changed without the knowledge of the person served unless the person served has waived in writing such consent.

Methadone or LAAM should be continued as long as benefit is derived from the treatment and the person served desires continued treatment. Therefore, there is no limit on the duration of treatment or dosage levels unless clinically indicated. However, any time a dose greater than 100 mg. is provided, the justification for such daily dose shall be recorded in the record of the person served. Dosage may be adjusted when medication is switched from one formula to another when differences cause clinically relevant complaints. When determining dosage, knowledge of the relative purity of available street drugs in the local area should be considered.

27. The medical director should determine if a person is eligible for unsupervised take-home medication based on:

a. The absence of illicit opiate use.

b. The absence of abuse of alcohol and illicit drugs.

c. Regular program attendance.

d. The length of time and level of maintenance treatment.

e. Recent criminal activity.

f. Serious behavioral problems.

g. The stability of the home environment and social relationships.

h. The ability to safely store take-home medication.

i. The daily life schedule of the person served to include work, school, and family responsibilities and travel distance to program.

Interpretive Guidelines

27. The intent of this standard is to document in the record of the person served that the rehabilitative benefits of unsupervised use and decreasing frequency of program attendance outweigh the potential risk

of diversion.

27.a. Urine and other toxicological tests determine the absence of drugs.

28. Based on the clinical judgment of the physician, the quantity of unsupervised medication should not exceed:

a. A maximum of one unsupervised dose per week during the first ninety days of treatment.

b. A maximum of two unsupervised doses per week during the second ninety days of treatment.

c. A maximum of three unsupervised doses per week during the third ninety days of treatment.

d. A maximum of six unsupervised doses per week for the remainder of year one and year two.

e. A maximum of thirty unsupervised doses per month for year three and beyond.

Interpretive Guidelines

28. Providing medication for unsupervised use is based on the physician's judgment and the staff's assessment of the person's behavior while in treatment. The intent of this standard is to place a limit on the maximum unsupervised dose. However, the program may choose a different dosing pattern within the parameters of these standards, depending on the physician's clinical judgment. One time or temporary (usually not to exceed three days) unsupervised take home medication may be approved for documented family or medical emergencies or other exceptional circumstances. Unsupervised take-home medication should be labeled with the name of the program, address, telephone number, and packaged in conformance with federal regulations.

29. Medical withdrawal from methadone or LAAM should include:

a. Determining a schedule of withdrawal that is well tolerated by the person served and in accordance with sound medical practices.

b. Assurance that voluntary withdrawal would be discontinued and maintenance resumed in the event of impending relapse.

c. Reviews of the results of a recent pregnancy test.

d. Counseling and other support services increased and/or continued after medical withdrawal.

e. Provisions for continuing care after the last dose of methadone.

Interpretive Guidelines

29. Medical withdrawal refers to a medically supervised, gradual reduction or tapering of dose over time to achieve the elimination of tolerance and physical dependence to methadone or LAAM or other opioid agonist or partial agonist. Medical withdrawal refers to the withdrawal from methadone and not detoxification from other substances.

The term "medical withdrawal" was chosen because methadone should not be considered to be a "toxic" substance. These guidelines focus on persons who have been maintained on methadone or LAAM

pharmacotherapy, rather than focus on issues of medical withdrawal of opioid-addicted persons who are not eligible for methadone/LAAM therapy, or who do not elect this type of treatment. Involuntary withdrawal or "administrative withdrawal" is addressed in the section on legal issues which requires that due process be defined and followed. No schedule for dose reductions will fit all patients; some individuals tolerate more rapid withdrawal than others. The underlying goal is to have voluntary medical withdrawal reflect a humane partnership between the person served and the physician.

29.b. Voluntary withdrawal from methadone/LAAM therapy, as distinct from involuntary withdrawal and administrative withdrawal and other types of withdrawal, is initiated only when desired by the person served, in partnership with the physician.

30. When medical withdrawal is conducted against medical advice:

a. The program should document:

(1) Efforts taken by program staff members to avoid discharge.

(2) Reasons the person served is seeking discharge.

b. The record of the person served remains active for at least 30 days.

Interpretive Guidelines

30. While every effort should be made to retain persons in treatment, individuals have the right to leave treatment when they choose to do so.

[Ref. Sec. 4.A.2.]

31. Prior to the beginning of administrative withdrawal:

a. Efforts should be documented regarding referral or transfer of the person served to a suitable, alternative treatment program.

b. Due process procedures should be implemented with provisions for appeals or grievances.

Interpretive Guidelines

31. Ongoing multidrug abuse is not, in itself, a reason for discharge unless the person served refuses recommended and more intensive levels of treatment. Involuntary administrative withdrawal should be a decision when all other efforts at retention have failed. This type of withdrawal is typically brief and often does not extend beyond thirty days. Reasons for administrative withdrawal may include non-payment of fees or conduct or behavior considered
to have an adverse effect on the program, staff members, or person served such as:

- Violence or threat of violence.
- Dealing drugs.
- Repeated loitering.
- Flagrant noncompliance resulting in an observable, negative impact on the program, staff members, or other persons served.
- Incarceration or other confinement.

31.a. Programs should attempt to refer or transfer the person to another treatment facility. The program should have a detailed relapse prevention plan in place prior to discharge. The person served and

counselor should review this plan. It is also recommended that the last dose of methadone not be given on the last day of treatment.

32. Documentation should be maintained regarding each person's condition during withdrawal to include:

a. Symptoms of medical and emotional distress.

b. Significant signs.

c. Actions taken, including those taken to avoid discharge.

d. Progress of the person served.

Interpretive Guidelines

32. Since withdrawal is primarily a medical protocol, clear documentation in the form of treatment plans and progress notes need to be maintained.

32.a. During discharge, individuals are monitored for signs and symptoms and mental illness.

33. The persons served should receive counseling designed to motivate the continuation of services following medical withdrawal.

Interpretive Guidelines

33. It is important to begin the treatment process as soon as possible and begin intervening at a point when the person served may be most open to counseling. The intent of this standard is to ensure that when the persons are being treated for physical withdrawal, they are also engaged in initial counseling to encourage the continuation of services.

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